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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,019	10/17/2000	Max Rombi	017753-128	4184

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EXAMINER

PATTEN, PATRICIA A *24*

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/601,019

Applicant(s)
Rombi, M.

Examiner
Patricia Patten

Art Unit
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 16, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5, 16, and 25-28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 16, and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1, 3, 5, 16 and 25-28 are pending in the application and were presented for examination on the merits.

It is noted that the Office Action dated 11/29/02 was not official because Applicant had applied for a Suspension prior to mailing of the Office Action. A Supplemental Response to the Office Action dated 11/29/02 along with the Declaration under 37 C.F.R 1.132 have been fully considered and will be discussed *infra*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasuda et al. (1991). Claims 1, 3, 25 and 26 are drawn to an extract of green tea

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comprising 20-50% of epigallocatechol gallate (EGCG) and 5-10% of caffeine. Claims are further drawn to wherein the extract comprises 20-30% by mass of EGCG and wherein the extract is an 80% alcoholic extract.

Yasuda et al. (1991) disclosed a composition for decreasing halitosis which contained an 80% alcoholic extract of green tea (Abstract). Applicants disclosed that an 80% alcohol extract inherently contains 20-30% catechols and 5-10% caffeine. Thus, the product must be the same if the steps for preparing are the same:

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are **produced by identical or substantially identical processes**, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

In this case, because Yasuda et al. disclosed the 80% alcoholic extract from green tea, it *must have* inherently contained the claimed percentages of EGCG and caffeine. The inherency of the percentages of the constituents present in the extract flows logically from the Yasuda et al. reference, since it is the same plant material being extracted with the same solvent. Herein is evidence of inherency, and therefore, Yasuda et al. need not explicitly disclose the exact chemical nature of the extract.

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Applicant has replied to the unofficial Office Action sent on 11/29/02 which also contained this rejection. Applicant's arguments will be answered:

The Declaration submitted 1/16/2003 shows that different types of green tea provide for varying caffeine and catechines upon ethanolic extraction. Applicant further argues that "green tea" is merely a generic term for an extremely broad class of at least several hundred plant varieties...all green teas are not created equal, at least with respect to the catechol and caffeine content" (p.2-Arguments). However, as pointed out in previous Office Actions, a particular type of green tea *was not disclosed* in the original Specification as filed, nor is any particular type of green tea actually present in the claims. Applicant states that "The results in Tables 1 and 2 further demonstrate that it cannot be assumed or predicted that a particular green tea will have the synergistic thermogenic amounts or proportions of caffeine and catechols" (Declaration). However, the Instant specification clearly teaches that an 80% ethanolic extract of green tea provides for the Instantly claimed amounts of caffeine and catechols. This information was present in the Instant specification as filed, and therefore is not an assumption.

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Applicant states that 'AR-25' which is the product of the Invention has been marketed, and is projected to make significant earnings. However, based upon the Specification, an 80% alcoholic extract will produce the Invention. Because Yasuda et al. taught an 80% extract of green tea, it is deemed that the above mentioned claims are anticipated by Yasuda et al.

Applicant argues that Yasuda et al. "has given no indication of such a content" (referring to the claimed amounts of caffeine and catechol). Again, this is considered an inherent property of the product produced by Yasuda et al. due to the teachings in the Instant specification. Applicant further adds that 'Yasuda adds these separately fractionated catechins to chewing gum to determine the effect of halitosis, an effect so remote from the presently claimed invention so as to be completely unrelated" (p.4, Arguments). However, Yasuda did prepare the composition, and therefore anticipated the claimed invention, regardless of the intended use of the composition. Further, it is deemed that Yasuda is pertinent prior art since Yasuda teaches medicinal preparations made from alcoholic extracts of green tea, as does the Instant specification.

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Claim Rejections - 35 USC § 103

Claims 5, 16 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al. (1991) as applied to claims 1, 3, 25 and 26 above. Claims 5, 16 and 26-28 are drawn to specific milligram amounts of EGCG and caffeine which are present in a composition.

The teachings of Yasuda et al. (1991) were discussed *supra*.

Yasuda et al. did not specifically disclose the milligram amounts of EGCG and caffeine which are recited in the Instant claims.

The ordinary artisan would have recognized that the claimed amounts of EGCG and caffeine were all within the ratio of EGCG to caffeine which are found in the 80% alcoholic extract of green tea (i.e., 20%:5% = 4:1 for example).

One of ordinary skill in the art would have been motivated to have extracted green tea with a 80% solution on a large scale to produce the claimed amounts of EGCG and caffeine in order to have mass produced the product. The ordinary artisan would have expected that large-scale extractions of green tea would have been more

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cost efficient and less time consuming than more frequent extractions of small amounts of green tea.

Applicant argues that the remarks made under the Arguments pertaining to the 35 U.S.C. 102 (b) rejections apply to the rejections under 35 U.S.C. 103 (a). However, as pointed out *supra*, the claims remain rejected over the prior art in light of the teachings in the Instant specification.

Applicant further argues that the rejection is not relevant to the claims, and further that Applicant is not clear with regard to the Examiner's comment on large scale extraction.

Applicant has taught in the Instant specification that an 80% alcohol extract of green tea will produce a specific ratio of caffeine to catechol. Therefore, 1 gram of green tea will produce the same percentage at a certain amount, as will 1 Kg of green tea although at a different amount. Scaling up or down a procedure is routine in the art. Therefore, because the 80% alcoholic extract of green tea produces a specific ratio of caffeine to catechols, the ordinary artisan would have expected that some amount of green tea would have produced the Instantly claimed amounts because they are in proportion to the ratio of caffeine to catechol as taught in the Instant specification. An analogous example would be a claimed composition of A and B wherein the ratio of A

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to B was 2:1 which was known in the art. A composition comprising 6:3 may not be the *exact* composition, however is obvious in light of the consideration that scaling-up a composition is known in the art. Since the 80% alcoholic extract was known in the art, and known to have medicinal properties, it would have been obvious to have performed this extraction on various amounts of green tea in order to perform small scale experiments as well as large scale production. In the art of manufacturing nutritional products, it is common to produce large amounts of ingredients (batches) from which smaller proportions are taken to package for sale. For example, if one performed an 80% alcohol extract on 1000 mg of green tea, a product comprising a specific ratio of caffeine to catechol would be obtained. No matter what amount was taken from this batch of extract, *the ratio would remain the same*.

It appears that overall, Applicant contends that the particular percentages of green tea, which Applicant refers to as synergistic, were produced by a particular variety of green tea, and therefore the prior art could not have taught this information thereby rendering the rejections moot. However, the application teaches that an 80% alcoholic extract of *green tea* produces the ratios of caffeine to catechol, and does not teach any specific variety of green tea.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Patricia Patten

A handwritten signature in black ink, appearing to read "Patricia Patten". The signature is written in a cursive style with a large initial "P" and a long horizontal stroke extending to the right.